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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/662,061 | 09/12/2003 | Christopher J. Horvath | 1855.1069-006 | 1933 |

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EXAMINER

GAMBEL, PHILLIP

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1644

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,061

Applicant(s)

HORVATH ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 10, 12, 14, 16, 18, 22, 23 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3, 5-8, 10, 12, 14, 16, 18, 22, 23 and 34-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Reply To Restriction Requirement, filed 7/28/06, is acknowledged.

As requested by applicant for the reasons set forth in the Reply, the previous Restriction Requirement, filed 7/3/06, has been vacated.

2. Applicant's Preliminary Amendment, filed 3/31/04, has been entered.
Claims 4, 9, 11, 13, 15, 17, 19-21, 24-33 have been canceled.

Claims 1-3, 5-8, 10, 12, 14, 16, 18, 22, 23 and 34-39 are pending.

3. In the interest of compact prosecution, the species election is based upon integrin antagonists that are antibodies that bind CD18 integrins as the first therapeutic agent and antagonists of chemokine receptor function that are antibodies that bind CCR2.

However, the instant specification discloses a number of "integrin antagonists" and "antagonists of chemokine receptor function", which contemplates a variety of distinct molecules (e.g. small organic molecules, antibodies, peptides, peptidomimetics, etc.) and a variety of distinct specificities (e.g., distinct integrins, selectins, immunoglobulin superfamily molecules as integrin specificities and/or distinct chemokines / chemokine receptors such as CCR2 or CCR3, CXCR3 that are "antagonists of chemokine receptor function") (see Therapeutic Agents on pages 10-23 of the instant specification). The examiner notes that these targeted specificities do not share a substantial structural feature essential to a common utility and, in turn, the antibodies that bind said specificities also do not share a substantial structural feature essential to a common utility.

Applicant is invited to limit the claims to the elected species.

If claims to structurally distinct specificities and antagonists are presented during the course of prosecution, they will be subject to further restriction or species requirements.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

wherein the first therapeutic agent is:

- A) an anti-CD11a/CD18 antibody,
- B) an anti-CD11b/CD18 antibody
- C) an anti-CD11c/CD18 antibody
- D) an anti-CD11d/CD18 antibody
- E) an anti-CD18 antibody that inhibits binding of ICAM-1
- F) an anti-CD11a/CD18 antibody that inhibits binding of ICAM-2 or
- G) an anti-CD11a/CD18 antibody that inhibits binding of fibrinogen.

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AND

wherein the second therapeutic agent is:

- H) an anti-CCR2 antibody that inhibits binding of MCP-1,
- I) an anti-CCR2 antibody that inhibits binding of MCP-2,
- J) an anti-CCR2 antibody that inhibits binding of MCP-3,
- K) an anti-CCR2 antibody that inhibits binding of MCP-4, or
- L) an anti-CCR2 antibody that inhibits binding of MCP-5.

These targeted specificities as well as the antagonists of the targeted specificities as they read on the claimed CD18-specific antibodies antagonists as the first therapeutic agent and of CCR2-specific antibody antagonists as the second therapeutic agent do not share a substantial structural feature essential to a common utility.

Applicant is required to elect a specific anti-CD18 antibody antagonist from (A) – (G) for the first therapeutic agent AND to elect a specific anti-CCR2 antibody antagonist from (H) – (L) for the second therapeutic agent.

Applicant is invited to clarify the antibody specificities in the context of whether the antibody specificities are overlapping and/or obvious over one another.

For example, would it be inherent or obvious for an antagonistic anti-CD18 antibody to block binding of ICAM-1 and ICAM-2 or whether these are distinct epitopic specificities.

Also, applicant is invited to clarify whether an anti-(CD11aCD18 antibody is intended to be an anti-CD11a antibody, an anti-CD18 antibody or an antibody that binds a unique epitope of CD11a/CD18.

Similarly, would it be inherent or obvious for an antagonistic anti-CCR2 antibody to block binding of MCP-1 and MCP-2 or whether these are distinct epitopic specificities.

Again, as noted above, this species election is limited to the claimed anti-CD18 and anti-CCR2 antibody specificities. If additional integrin antagonists or and antagonists of chemokine receptor function are added during prosecution, either an additional restriction or species requirement will be set forth, as the first and second therapeutic agents comprise an array of molecules and specificities that not share a substantial structural feature essential to a common utility.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species of both a "cytokine" and a "cancer therapeutic agent" for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18 and 34 are generic.

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5. In addition to the election of species set forth in Section 4 above,

this application contains claims directed to the following patentably distinct species of the claimed invention: wherein the vascular procedure is selected from those recited in claims 3 and 38 or disclosed on page 25, paragraph 1 of the instant specification.

These species are distinct because the procedures differ in ingredients, process steps and endpoints endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species of a vascular procedure (e.g. *angioplasty*) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18 and 34 are generic.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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